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EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/520,419

Applicant(s)

MEEK ET AL.

Examiner

Carolyn M Bleck

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection; whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 06 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 1-4, 7-10 and 21-23.Claim(s) withdrawn from consideration: NONE.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____



JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

**Continuation of 5. does not place the application in condition for allowance
because:**

(A) Applicant argues that the applied prior art, namely Wong, fails to teach or suggest certain features of claim 1. In particular, the Applicant argues that Wong fails to teach or suggest the steps of determining whether a certain predictive factor is itself indicative of a risk and assigning a first or second dichotomous value to a predictor factor in response to the determining step.

In response, the Examiner respectfully submits that Wong discloses a method of identifying patients at high risk of adverse health outcomes (col. 1 lines 9-12, col. 2 lines 31-45, col. 3 lines 42-48, col. 5 lines 13-25 and 31-40, and col. 15 lines 58-67) comprising:

(a) receiving (reads on "collecting"), storing, and extracting information from a patient record (reads on "individual") for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, and col. 17 line 49 to col. 18 line 4);

(b) assigning, based upon information from a patient record, a separate value to each predictor of the set of predetermined criteria or predictors (Abstract lines 1-24, col. 2 lines 61-62, col. 4 lines 62-66, col. 5 lines 3-12, col. 6 lines 44-51 and lines 64-67, col. 8 lines 18-22, col. 12 lines 27-39, and col. 13 lines 1-41);

(c) generating, based upon a prediction model and the separate values assigned to the predetermined set of criteria or predictors, risk subgroups (reads on "risk level") of the patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (Fig. 6A-6B, Abstract lines 1-24, col. 1 lines 48-60, col. 2 lines 38-45 and lines 64-67, col. 3 lines 1-7, col. 3 lines 42-48, col. 4 line 65 to col. 5 line 3, col. 5 lines 13-25, col. 6 lines 44-63, col. 8 lines 33-35, col. 12 lines 7-18, col. 13 lines 51-60, and col. 18 lines 15-23 and lines 28-41);

(d) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

(e) assigning, based upon information, a first dichotomous value, such as "1", to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(f) assigning, based upon information, a second dichotomous value, such as "0", to the separate value for the first predictor in response to defining that the first predictor

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is not an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54).

Furthermore, the Examiner respectfully submits that Applicant is responsible for the full teachings of the reference. The Examiner notes the following passages relied upon for further guidance regarding the interpretation of the Wong reference with regards to the steps of assigning first and second dichotomous values. Note Wong's teachings disclosing using independent variable representing potential predictors of adverse health outcomes, wherein the independent variables of interest including assigning a yes or no (Y/N) to the following variables: ischemic heart disease, diabetes, adverse lifestyle diagnosis, cardiac dysrhythmias, other heart disease, and hypertensive disease (col. 12 line 26 to col. 13 line 18). The Examiner respectfully submits these independent variables are input into the prediction model (col. 17 line 49 to col. 18 line 23). However, it is noted these variables in the form of Y/N variables cannot be input into a model in this form as letters, and therefore would be entered into the model as a form of a value, such as a number (i.e., 0 or 1). Thus, it is the position of the Examiner that Wong discloses assigning values to a predictor value, and therefore the rejection is maintained.

Furthermore, it is noted the specification provides no strict definition of the term "dichotomous value", nor was the Examiner able to find any specific portion of the

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specification providing a positive definition of the claimed "dichotomous value". Thus, the Examiner has given the claim language the broadest interpretation and has applied art accordingly with regards to variables being a form of dichotomous value, and as discussed above.

Continuation of 7. For purposes of Appeal, the proposed amendments will be entered and an explanation of how the new or amended claims would be rejected is provided below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (5,976,082).

(A) As per claim 1, Wong discloses a method of identifying patients at high risk of adverse health outcomes (col. 1 lines 9-12, col. 2 lines 31-45, col. 3 lines 42-48, col. 5 lines 13-25 and 31-40, and col. 15 lines 58-67) comprising:

(a) receiving (reads on "collecting"), storing, and extracting information from a patient record (reads on "individual") for a predetermined set of criteria or predictors

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(Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, and col. 17 line 49 to col. 18 line 4);

(b) assigning, based upon information from a patient record, a separate value to each predictor of the set of predetermined criteria or predictors (Abstract lines 1-24, col. 2 lines 61-62, col. 4 lines 62-66, col. 5 lines 3-12, col. 6 lines 44-51 and lines 64-67, col. 8 lines 18-22, col. 12 lines 27-39, and col. 13 lines 1-41);

(c) generating, based upon a prediction model and the separate values assigned to the predetermined set of criteria or predictors, risk subgroups (reads on "risk level") of the patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (Fig. 6A-6B, Abstract lines 1-24, col. 1 lines 48-60, col. 2 lines 38-45 and lines 64-67, col. 3 lines 1-7, col. 3 lines 42-48, col. 4 line 65 to col. 5 line 3, col. 5 lines 13-25, col. 6 lines 44-63, col. 8 lines 33-35, col. 12 lines 7-18, col. 13 lines 51-60, and col. 18 lines 15-23 and lines 28-41);

(d) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

(e) assigning, based upon information, a first dichotomous value, such as "1", to the separate value for the first predictor in response to defining that the first predictor is

an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(f) assigning, based upon information, a second dichotomous value, such as "0", to the separate value for the first predictor in response to defining that the first predictor is not an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54).

(B) As per claim 8, Wong discloses defining, based upon risk subgroups (reads on "risk level"), whether a high risk exists of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-25, col. 5 lines 31-40, col. 6 lines 44-51, and col. 13 lines 51-60), and defining, based upon information from a patient, a targeted intervention for a patient in response to defining that a high risk exists of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5

lines 1-25, col. 5 lines 31-65, col. 6 lines 44-51, col. 13 lines 51-60, and col. 15 lines 58-67).

(C) As per claim 9, Wong discloses generating, based upon separate values assigned to each predictor and a model generated using multiple logistic regression, a risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30, col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 51-60, and col. 14 lines 49-58).

(D) As per claim 10, Wong discloses generating, based upon separate values assigned to the set of predictors and a model generated using multiple logistic regression, a probability or likelihood indicating the risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30, col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 51-60, and col. 14 line 60 to col. 15 line 67).

(E) As per claims 21-23, Wong discloses:

(a) determining a resulting subset of variables from a set of variables or predictors best reflecting a correlation to patients who are at high risk for adverse health outcomes, consequently, resulting in substantial use of health care resources (e.g., funds) (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 38-61, col. 3 lines 58-67, col. 4

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lines 24-34, col. 4 line 61 to col. 5 line 25, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, col. 8 line 65 to col. 9 line 5, and col. 17 line 49 to col. 18 line 4); and

(b) defining points A, B, and C, wherein A represents the farthest past event, wherein B represents the present, wherein C can be defined by the last day for which an individual is still enrolled and eligible for benefits within a health plan, wherein $A < B < C$, and wherein the prediction of congestive heart failure hospitalization includes defining a time period between B and C such as 6 months used to predict CHF hospitalization within the next 6 months (col. 13 line 48 to col. 14 line 48). It is noted that the prediction time period of 6 months as discussed above in Wong is a "prospective time span."

The remainder of claims 21-23 repeat the same limitations as claim 1, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1 above, and further in view of Mebane (5,486,999).

(A) As per claim 2, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong fails to expressly disclose presenting an individual with a self assessment questionnaire designed to elicit information from an individual for a predetermined set of predictive factors. However, Wong includes receiving (reads on “collecting”), storing, and extracting information from a patient data record or file (reads on “individual”) for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4). Note, Wong receiving information in a patient file is considered to be a form of eliciting information from an individual.

Mebane discloses presenting a patient with a Lifestyle Questionnaire designed to determine selected lifestyle characteristics of the patient, wherein the questionnaire contains a set of input variables used to determine health care utilization (Fig. 4A, col. 2 lines 10-28, col. 5 lines 1-67, col. 6 Table 1, and col. 16 –18 Appendix A).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned component of Mebane within the method taught by Wong with the motivation of improving the quality of treatment and outcomes for patients and reducing the cost for health care services by analyzing information about a patient’s medical history and record (Wong; col. 2 lines 38-45).

(B) As per claim 3, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong discloses a predetermined set of criteria or predictors, wherein the predictors include past healthcare use factors, such as number of hospitalizations, emergency services, or physician office visits, demographic factors, such as gender or age, and disease factors, such as diabetes or congestive heart failure (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-52, col. 5 lines 1-12, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-67, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4).

In addition, insofar as Applicant recites “predetermined set of predictive factors consisting of...,” it is irrelevant whether or not Wong and Mebane disclose every single statement recited in the claim.

The remainder of claim 3 repeats the same limitations as claim 2, and is therefore rejected for the same reasons given for claim 2, and incorporated herein. The motivation for combining Mebane with Wong is given above in claim 2, and incorporated herein.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1 above, and further in view of Silver (6,269,339).

(A) As per claim 4, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong discloses receiving (reads on “collecting”), storing, and extracting information from a patient data record or file (reads on “individual”) for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4).

Wong fails to expressly disclose presenting, to a web browser, a questionnaire that elicits information from an individual for a predetermined set of predictive factors, and receiving the information via a web browser in response to presenting the questionnaire.

Silver discloses presenting on a client computer system, over the Internet an interface for data input (reads on “web browser”), wherein the interface includes a questionnaire for inputting information from a patient for a set of relative risk factors (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), and receiving the information at a server over the Internet in response to presenting the questionnaire through an interface for data input (reads on “web browser”) (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), wherein the client computer system and the server communicate using the NetBIOS protocol (col. 7-8).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components of Silver within the method taught by Wong with the motivation of improving the quality of treatment and

outcomes for patients and reducing the cost for health care services by analyzing information about a patient's medical history and record (Wong; col. 2 lines 38-45), and providing a convenient means and decreasing the time to submit, update, and access information (Silver; col. 3 lines 49-51, col. 4 lines 48-64, and col. 8 lines 15-40).

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1.

(A) As per claim 7, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong fails to expressly disclose determining whether each predictive factor of a set of predictive factors is indicative of a high risk of an individual utilizing healthcare services at a predetermined level within a prospective time span, assigning a first dichotomous value or a "1" to each separate value of each predictive factor of the set of predictive factors that is determined to be indicative of a high risk, and assigning a second dichotomous value or a "0" to each separate value of each predictive factor of the set of predictive factors that is determined to not be indicative of a high risk.

However, Wong discloses the following for a single predictor:

(a) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col.

7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

(b) assigning, based upon information, a first dichotomous value, such as "1", to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(c) assigning, based upon information, a second dichotomous value, such as "0", to the separate value for the first predictor in response to defining that the first predictor is not an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54).

As per the recitation of additional or separate dichotomous values, the courts have broadly held that the duplication of parts is obvious. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). As such, these changes do not present a patentable distinction over the applied prior art of record.

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